

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)
PHARMACY, INC. PRODUCTS LIABILITY)
LITIGATION)
_____)

MDL No. 2419
Dkt. No 1:13-md-2419 (RWZ)

THIS DOCUMENT RELATES TO:)

All Cases)

STOPNC DEFENDANTS':

**(1) OPPOSITION TO PLAINTIFFS' STEERING COMMITTEE'S MOTION TO COMPEL
DOCUMENTS AND INFORMATION FROM
STOPNC'S PHARMACY CONSULTANT, MICHAEL O'NEAL [DOC. NO. 2437]**

AND

**(2) RESPONSE IN SUPPORT OF MOTION FOR PROTECTIVE ORDER
FILED BY MICHAEL O'NEAL [DOC. NO. 2469]**

Defendants Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; and Vaughan Allen, MD, (collectively "STOPNC Defendants"), file this brief to state their position on the application of the privilege found in Tennessee's Patient Safety and Quality Improvement Act to communications and documents related to Michael O'Neal's pharmacy consulting for STOPNC.¹ Specifically, this brief *opposes* the Plaintiffs' Steering Committee's Motion to Compel Compliance with Subpoena to Michael O'Neal² and *responds in support of* the Motion for Protective Order for Michael O'Neal.³

¹ TENN. CODE ANN. §§ 63-1-150, 68-11-272.

² Doc. 2437.

³ Doc. 2469.

1. Introduction

The PSC's Motion to Compel asks the Court to order Mr. O'Neal, a pharmacist and STOPNC's retained consultant for pharmacy issues, to turn over documents and disclose communications related to his quality improvement consulting for STOPNC. The Motion should be denied because the communications and the related documents between Mr. O'Neal and STOPNC fall squarely within the privilege created by Tennessee's Patient Safety and Quality Improvement Act ("TPSQIA" or the "Act"). Mr. O'Neal's briefings on this issue⁴ explains why the Act's privilege applies.⁵

The STOPNC Defendants file this brief on the dispositive point of issue preclusion, which the PSC's briefing glosses over and Mr. O'Neal's does not address. Issue preclusion *plainly bars* the PSC's unabashed attempt to re-litigate this *exact* issue, an issue that has already been decided, on the merits, by a competent court. Re-litigating this issue runs plainly counter to the letter and spirit of *res judicata* and, specifically, issue preclusion.

Because the Tennessee state court has already decided this exact issue on the merits for the same parties, the Court must deny the Motion to Compel and grant the Motion for Protective Order.

⁴ Docs. 2469; 2478.

⁵ The STOPNC Defendants apparently disagree with Mr. O'Neal on one point: The 2011 Act's privilege *does* apply retroactively. Tennessee's trial courts have consistently applied it retroactively. See Order, Circuit Court for Coffee County, 12/3/14 (applying TPSQIA retroactively); Order, Circuit Court for Davidson County, 10/22/12 (applying TPSQIA retroactively); Order, Circuit Court for Marion County, 7/26/12 (applying TPSQIA retroactively) (all attached as exhibit 1). The 2011 version of the privilege (the TPSQIA) was passed specifically to remedy the Tennessee Supreme Court's holding in *Lee Med., Inc. v. Beecher*, 312 S.W.3d 515, 526 (Tenn. 2010) (see articles at <http://www.h3gm.com/resources-alerts-Tennessee-Patient-Safety-And-Quality-Improvement-Act.html>; <http://www.bakerdonelson.com/out-of-the-ashes-tennessee-patient-safety-and-quality-improvement-act-of-2011-12-13-2011/>; <http://www.latlaw.com/index.php/firm-news-articles/articles-2011/56-legislative-update-the-tennessee-patient-safety-and-quality-improvement-act>). As a remedial statute, it must be applied retroactively. *Henderson v. Ford*, 488 S.W.2d 720, 721 (Tenn. 1972); see *Nutt v. Champion Int'l Corp.*, 980 S.W.2d 365, 368 (Tenn. 1998). Regardless, both versions of the privilege apply. See Doc. 2469.

- 2. *Res judicata* – a general doctrine intended to further judicial economy, prevent inconsistent decisions, and encourage reliance on previous adjudication – applies to individual issues previously decided via the sister doctrine of collateral estoppel / issue preclusion.**

This brief requires a review of the concepts of *res judicata*, collateral estoppel, and issue preclusion.

Res judicata “broadly refers to an issue that has been definitively settled by judicial decision.”⁶ *Res judicata* encompasses both claim preclusion and issue preclusion, also known as collateral estoppel.⁷ Collateral estoppel, or issue preclusion, bars the re-litigation of *an issue* that has already been decided in a prior suit between the same parties.⁸

Courts have long recognized the important public policy considerations underlying the doctrine of issue preclusion: to relieve parties of the cost of repeat litigation of the same issues; to conserve judicial resources; to prevent inconsistent decisions; and to encourage reliance on adjudication.⁹

⁶ *Regions Fin. Corp. v. March USA, Inc.*, 310 S.W. 3d 382, 392 (Tenn. Ct. App. 2009) (quoting BLACK’S LAW DICTIONARY 1336-37 (8th ed. 2004)).

⁷ *State v. Thompson*, 285 S.W.3d 840, 848 (Tenn. 2009).

⁸ *Thompson*, 285 S.W.3d at 848.

⁹ *Allen*, 449 U.S. at 94; *In re Sonus Networks, Inc. Shareholder Derivative Litig.*, 442 F. Supp. 2d 281, 288 (D. Mass. 2006); *Thompson*, 285 S.W.3d at 848.

3. The elements of issue preclusion under Tennessee law.

The party seeking to invoke the doctrine of issue preclusion¹⁰ has the burden of establishing:¹¹

1. The issue sought to be precluded is identical to the issue decided in an earlier suit;
2. The issue sought to be precluded was actually litigated and decided on the merits in the earlier suit;
3. The judgment in the earlier suit has become final;
4. The party against whom collateral estoppel is asserted was a party or is in privity with a party to the earlier suit; and,
5. The party against whom collateral estoppel is asserted had a full and fair opportunity in the earlier suit to litigate the issue now sought to be precluded.¹²

4. Issue preclusion bars the Plaintiffs from re-litigating the issue of whether the Act's privilege applies to the O'Neal communications and documents.

All five elements of issue preclusion are present.

a. The issue sought to be precluded is identical to a previously decided issue.

The first Tennessee cases against the STOPNC Defendants were filed in state court in 2013 and were litigated for months before being voluntarily dismissed, re-filed in federal court, and ultimately transferred to the Massachusetts federal court for multi-district litigation proceedings. Prior to the voluntary dismissal and re-filing in federal court, the same parties litigated the applicability of the Act's privilege to the O'Neal

¹⁰ This brief will use the term "issue preclusion," as its connotation makes more sense than "collateral estoppel."

¹¹ Tennessee's elements of issue preclusion should apply. See *Atlantic Marine Const. Co., Inc. v. U.S. Dist. Court for Western Dist. Of Texas*, 134 S.Ct. 568, 582 (2013) (holding that, when venue has been transferred for the convenience of the parties, the state law applicable in the original court also applies in the transferee court). Regardless, "[f]ederal issue preclusion doctrine and Tennessee issue preclusion doctrine are essentially identical." *In re Deb*, 2012 WL 1664235, *5, n. 12 (Bankr. N.D. N.Y. 2012).

¹² *Beatty v. McGraw*, 15 S.W.3d 819, 824-825 (Tenn. Ct. App. 1998).

documents and communications, the *same* issue the PSC asks the Court to reconsider here.

In the *Reed* case, the same lawyers involved in the MDL sought production of reports and communications between STOPNC and Mr. O’Neal. After two days of hearings on the issue (and other discovery issues), the Tennessee Circuit Court for Davidson County, Honorable Joseph Binkley, Jr., decided the “Plaintiff’s Motion to Compel production of reports and communications between St. Thomas Outpatient Neurosurgical (‘STOPNC’) and its pharmacist consultant, Michael O’Neal.”¹³ Judge Binkley found “that the reports and communications related to Mr. O’Neal’s pharmacy consulting for STOPNC are protected from discovery by the [TPSQIA].”¹⁴

Now, two-plus years later, the same plaintiffs and lawyers seek a second bite at the apple, asking this Court to find directly contrary to the Tennessee court and compel the testimony of Mr. O’Neal and the production of “all correspondence to, from, or between you and/or [STOPNC]...” related to compounding pharmacies, compounded pharmaceuticals, NECC, Depo Medrol, or methylprednisolone acetate.¹⁵

The issue to be precluded – the applicability of the TPSQIA’s privilege to the documents and communications related to O’Neal’s pharmacy consulting for STOPNC – is the exact issue that was decided in the state court litigation. Element 1 is met.

b. This issue was litigated and decided on the merits.

This issue was extensively litigated and decided on the merits in state court. Any argument to the contrary is absurd. The Tennessee court decided the issue “[a]fter

¹³ See Order, Tennessee Circuit Court for Davidson County, 5/31/13. It is attached as exhibit 2.

¹⁴ See Order, Tennessee Circuit Court for Davidson County, 5/31/13.

¹⁵ Doc. 2439-1.

reviewing the extensive briefing and supplemental findings and hearing arguments...on two separate days.”¹⁶ The Tennessee court considered:

1. Briefing by both sides¹⁷
2. Argument by both sides¹⁸
3. Affidavit testimony of Debra Schamberg
4. Affidavit testimony of Michael O’Neal
5. Documentary evidence, including the consulting agreements at issue.

Based on the extensive record and argument, the Tennessee court found that Mr. O’Neal was acting as a Quality Improvement Committee (“QIC”), as defined by the TPSQIA, and was performing one or more of the functions of a QIC under the statute as STOPNC’s pharmacist consultant.¹⁹ The Court also found that Ms. Schamberg was acting as a QIC when receiving Mr. O’Neal’s reports and evaluations.²⁰

This was not a two-line order. The Tennessee court issued a detailed order. In it, the Tennessee court specifically noted the policy behind the TPSQIA’s privilege:

At the outset of its ruling, the Court acknowledges that:

It is the policy of this state to encourage the improvement of patient safety, the quality of patient care and the evaluation of the quality, safety, cost, processes and necessity of healthcare services by hospitals, healthcare facilities and healthcare providers. Tennessee further recognizes that certain protections must be available to these entities to ensure that they are able to effectively pursue these measures.

The Court further recognizes that this policy was also evident in Tennessee’s previous “peer review” statute.” The Tennessee General Assembly has made it clear that it intends to protect these stated policies by extending privilege and protection from discovery to documents and communications related to quality improvement and peer review functions. Confidentiality in these functions is essential.

¹⁶ See Order, Tennessee Circuit Court for Davidson County, 5/31/13.

¹⁷ This included the Plaintiff’s Motion to Compel, STOPNC’s Response, and the Plaintiff’s Reply. All of the briefing is attached as exhibit 3 to this brief.

¹⁸ A copy of the 194-page hearing transcript is attached as exhibit 4.

¹⁹ See Order, Tennessee Circuit Court for Davidson County, 5/31/13.

²⁰ See Order, Tennessee Circuit Court for Davidson County, 5/31/13.

The Court finds that, in order to carry out these stated goals, healthcare providers and others engaged in the quality improvement process must be able to evaluate and critique healthcare services, without fear that such evaluations and criticisms will be used against healthcare providers at a subsequent judicial proceeding. To that end, those activities must be kept confidential and must be privileged from disclosure in discovery.²¹

After applying the text of the law and considering the policy behind the law, the Tennessee court found that communications and reports “connected with Mr. O’Neal’s activities as STOPNC’s pharmacist consultant” were protected from discovery.²²

The Tennessee Order denying the Motion to Compel clearly demonstrates that the matter was decided on the merits. It references the extensive briefing and argument of the parties and specifically cites the policy concerns behind the TPSQIA, the type of records protected by the TPSQIA, analysis regarding whether Mr. O’Neal was acting as a “Quality Improvement Committee,” and analysis regarding whether STOPNC was engaged in quality improvement activities.

This issue was thoroughly litigated and decided on its merits. Element 2 is present.

c. The previous “judgment” (*i.e.*, decision on the issue) was final.

Because the party invoking issue preclusion is only seeking to bar the re-litigation of an *issue* (as opposed to *claim* preclusion), courts must take a more flexible approach to the finality element and look at whether the *issue* was fully litigated and decided with finality. The concept of a “final judgment,” as it applies to issue preclusion, does not mean a judgement “which ends the litigation and leaves nothing for the court to do but

²¹ See Order, Tennessee Circuit Court for Davidson County, 5/31/13.

²² See Order, Tennessee Circuit Court for Davidson County, 5/31/13.

execute the judgment.”²³ It simply means that the *issue* was fully litigated and the court decided it with an element of finality.

*U.S. v. McGann*²⁴ is a New York case, but its language is instructive on the application of the “finality” element in the context of issue preclusion. In *McGann*, the Government filed a claim against the defendant for breach of fiduciary duty related to misuse of government funds.²⁵ The defendant argued that the timeliness of the claim had already been decided, and thus issue preclusion barred re-litigation of the issue.²⁶ The district court analyzed what constitutes finality for purposes of *issue* preclusion, as opposed to *claim* preclusion.²⁷

The district court noted that the word “final” is a word with many meanings; and, for the purposes of *issue* preclusion, final judgment “includes any prior adjudication of an issue in another action that is determined to be sufficiently firm to be accorded conclusive effect.”²⁸ The district court explained that, to define “final judgment” in its strictest sense when considering issue preclusion, can create “needless duplication of effort and expense....”²⁹

The *McGann* district court cited to a four-part test to determine whether a prior decision on an issue is “final” in the context of issue preclusion:

1. Whether the prior decision was “adequately deliberated and firm” and not “avowedly tentative;”
2. Whether the parties were fully heard;
3. Whether the court supported its decisions with a reasoned opinion; and,

²³ *Lummus Co. v. Commonwealth Oil Ref. Co.*, 297 F.2d 80, 89 (2nd Cir. 1961).

²⁴ *U.S. v. McGann*, 951 F. Supp. 372 (E.D. N.Y. 1997).

²⁵ *Id.* at 373-79.

²⁶ *Id.* at 379-80.

²⁷ *Id.* at 380-82.

²⁸ *Id.* at 381 (citing to RESTATEMENT, SECOND, JUDGMENTS).

²⁹ *Id.* at 380-81.

4. Whether the decision was subject to appeal or was in fact appealed.³⁰

The district court in *McGann* cited to *Lummus Co. v. Commonwealth Oil Refining Co.*, the “leading case” on the issue of finality in the context of issue preclusion.³¹ The *Lummus* court explained that finality in the context of issue preclusion “turns upon such factors as the nature of the decision (*i.e.* that it was not avowedly tentative), the adequacy of the hearing, and the opportunity for review.”³² As such, “finality” in the context of issue preclusion “may mean little more than that the litigation of a particular issue has reached such a stage that a court sees no really good reason for permitting it to be litigated again.”³³

As illustrated by the language in *McGann*, the primary factor when considering finality in the context of issue preclusion is whether the **issue** has been **fully litigated**, not how the prior case resolved. The common sense notion that, once an issue has been fully litigated by the parties and decided, it should not be re-litigated in a different court, is universally accepted in every federal circuit and Tennessee. See *Zdanok v. Glidden Co.*, 327 F.2d 944, 955 (2nd Cir. 1964) (“[d]ealing with this very question of the kind of finality of judgment necessary to create an estoppel, we pointed out, quite recently, that collateral estoppel does not require a judgment ‘which ends the litigation ... and leaves nothing for the court to do but execute the judgment,’ ... but includes many dispositions which, though not final in that sense, have nevertheless been **fully litigated**”) (emphasis added); *Jean Alexander Cosmetics, Inc. v. L’Oreal USA, Inc.*, 458 F.3d 244, 253 (3rd Cir. 2006) (“[a]pplying issue preclusion to independently sufficient

³⁰ *Id.* at 381 (citing to RESTATEMENT, SECOND, JUDGMENTS).

³¹ *Id.* at 381.

³² *Lummus Co. v. Commonwealth Oil Ref. Co.*, 297 F.2d 80, 89 (2nd Cir. 1961).

³³ *Lummus*, 297 F.2d at 89.

alternative findings furthers the basic objectives of the doctrine...Denying preclusive effect to a finding that would support a court's judgment merely because the case was disposed of on other grounds as well would result in the inefficient use of private and public litigation resources. Courts routinely decide cases on multiple grounds, each of which has been **fully litigated...**) (emphasis added); *Rimmer v. Fayetteville Police Dept.*, 567 F.2d 273, 276 (4th Cir. 1977) (collaterally estopping plaintiff from re-litigating an issue in a civil rights action that had previously been **fully litigated** during the course of his related criminal trial); *Chemetron Corp. v. Bus. Funds, Inc.*, 682 F.2d 1149, 1191 (5th Cir. 1982) ("[t]he finality requirement does not necessarily demand the ministerial act of executing a judgment. It does not elevate form over substance in that fashion – the accurate definition of 'finality' in the offensive collateral estoppel context is '**fully litigated.**'") (emphasis added); *Anderson v. City of Blue Ash*, 798 F.3d 338, 350 (6th Cir. 2015) (issue preclusion "generally prevent[s] parties from raising an argument that they already **fully litigated** in an earlier legal proceeding") (emphasis added); *Matter of Bulic*, 997 F.2d 299, 305 (7th Cir. 1993) (precluding the re-litigation of issues that have been **fully litigated**); *Pope v. Federal Home Loan Mortg. Corp.*, 561 Fed. Appx 569, 572 (8th Cir. 2014) (issue preclusion may be invoked for issues that have previously been **fully litigated**); *White v. City of Pasadena*, 671 F.3d 918, 931 (9th Cir. 2012) (allowing the plaintiff "to relitigate this issue now would be contrary to the public policy concerns underlying the issue preclusion doctrine, given that the issue has been **fully litigated...**") (emphasis added); *Cook v. Aagard*, 547 Fed. Appx 857, 859 (10th Cir. 2013) ("issue preclusion, 'prevents parties or their privies from relitigating facts and issues in the second suit that were **fully litigated** in the first suit") (emphasis added); In

re Bush, 62 F.3d 1319, 1323 (11th Cir. 1995) (issue preclusion “applies only to those issues which were ‘actually’ or ‘**fully**’ **litigated** in the prior action”) (emphasis added); *Geiselman v. U.S.*, 808 F. Supp. 86, 88 (D. Mass. 1992) (parties are collaterally estopped from re-litigating issues that have already been **fully litigated**); *Davidson v. Bredesen*, 330 S.W.3d 876, 887 (Tenn. Ct. App. 2009) (holding that a cause of action is barred by the doctrine of collateral estoppel when the issue has previously been “**fully litigated**”).

Applying the *McGann* four-part test here leads to a finding of “finality” of the adjudication of the issue in the state court case. The decision on the privilege issue was adequately deliberated and firm (factor 1), the parties were fully heard (factor 2), the court decided with a reasoned opinion (factor 3), and the issue was subject to appeal (factor 4).³⁴

The applicability of the TPSQIA to the O’Neal documents and communications was *fully litigated*, as evidenced by the extensive hearing of the issue and well-reasoned opinion. In the context of *issue* preclusion, this is sufficient finality to bar re-litigation. Element 3 is met.

d. The party against whom collateral estoppel is asserted was a party or is in privity with a party to the earlier suit.

There should be no dispute that Wayne Reed, the party to the earlier state suit, is also a party to the present MDL. Additionally, Mr. Reed’s attorney in the state action is actively engaged in prosecuting the Tennessee cases in the MDL.³⁵ Put simply, the same lawyers and parties litigated this issue previously. Element 4 is met.

³⁴ The Plaintiff could have sought an interlocutory appeal of the issue but did not. TENN. R. APP. PROC. 9.

³⁵ See e.g. Doc. 2300, Motion for Partial Summary Judgement Regarding Product Liability Claims Against Saint Thomas Outpatient Neurosurgical Center.

e. The party had a full and fair opportunity to litigate the issue.

Likewise, there should be no dispute that the Plaintiff had the opportunity to fully and fairly litigate this issue in the state action. As repeatedly stated, Mr. Reed's attorneys submitted numerous written briefs and participated in two days' worth of oral arguments. The only action Mr. Reed did not take was to seek an appeal of the court's Order denying his Motion to Compel, a decision Mr. Reed made voluntarily. As such, this condition of collateral estoppel has also been proven. Element 5 is met.

5. Conclusion

The STOPNC Defendants have carried the burden of establishing that the issue at hand has been fully litigated and the PSC should be precluded from litigating it again. The Court can and must credit the state court's reasoned decision after a full and fair litigation of the same exact issue. The PSC's Motion to Compel should be denied again, this time on the basis of issue preclusion, before the Court even needs to address the merits of the position.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 11th day of December, 2015.

/s/ Chris J. Tardio

Chris J. Tardio